

Moving Europe towards a
sustainable and safe railway
system without frontiers.

OPINION

ERA/OPI/2025-2

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS for

ESTONIA

regarding

seven (7) adopted and one (1) draft national rule setting
requirements on several operational aspects.

Disclaimer:

The present document is a non-legally binding opinion of the European Union Agency for Railways. It does not represent the view of other EU institutions and bodies, and is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

General Context

In line with Article 8 of Directive (EU) 2016/798 (Railway Safety Directive or RSD) and Articles 25 and 26 of Regulation (EU) 2016/796 (the Agency Regulation), this opinion covers the examination by the European Union Agency for Railways (hereinafter the Agency or ERA) of seven (7) Estonian adopted national rules and one (1) draft national rule setting requirements on several operational aspects.

Estonia notified the rules in the Single Rules Database (SRD) on 7 November 2024. The Agency assessed the rules and reached the conclusion on 6 January 2025 (also recorded in the SRD) that the notified adopted rules and draft rule contain requirements which according to the Agency's opinion:

- were not notified using the correct scope according to Article 8 of Directive (EU) 2016/798 on railway safety; and
- are not in line with the EU legal framework, mainly Regulation (EU) 2019/773 (TSI OPE) and Commission Delegated Regulation (EU) 2018/762 establishing common safety methods on safety management system requirements (CSM-SMS) ².

The Agency notified Estonia of the result of the assessment on 6 January 2025 via SRD and via email on 22 January 2025 and Estonia notified the Agency via SRD its rejection of the Agency's negative assessment of the seven (7) adopted national rules and one (1) draft rule on 5 March 2025.

This opinion is addressed to Estonia with a copy to the European Commission (EC).

It is uploaded in the Single Rules Database (SRD) and on the Agency's website.

Legal Background

Article 25 (2) and (3) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/20041 (Agency Regulation) sets out the following:

"2. Where, after the examination referred to in paragraph 1, the Agency considers that the draft national rules enable the essential requirements for railway interoperability to be fulfilled, the CSMs and TSIs in force to be respected and the CSTs to be achieved, and that they would not result in arbitrary discrimination or a disguised restriction on rail transport operations between Member States, the Agency shall inform the Commission and the Member State concerned of its positive assessment. In that case, the Commission may validate the rules in the IT system referred to in Article 27.

Where the Agency within 2 months of receipt of the draft national rule or within the extended time period agreed in accordance with paragraph 1 does not inform the Commission and the Member State concerned of its assessment, the Member State may proceed with the introduction of the rule without prejudice to Article 26.

3. Where the examination referred to in paragraph 1 leads to a negative assessment, the Agency shall inform the Member State concerned and ask it to state its position regarding that assessment. If, following that exchange of views with the Member State concerned, the Agency maintains its negative assessment, the Agency shall within a maximum period of 1 month:

(a) issue an opinion addressed to the Member State concerned, stating the reasons why the national rule or rules in question should not enter into force and/or be applied; and

(b) inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should not enter into force and/or be applied..."

Article 26 (3) of the Regulation (EU) 2016/796 sets out the following:

Where the examination referred to in paragraph 1 leads to a negative assessment, the Agency shall inform the Member State concerned and ask it to state its position regarding that assessment. If, following that exchange of views with the Member State concerned, the Agency maintains its negative assessment, the Agency shall within a maximum period of 1 month:

(a) issue an opinion addressed to the Member State concerned, stating that the national rule or rules in question has or have been the subject of a negative assessment and the reasons why the rule or rules in question should be modified or repealed; and

(b) inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should be modified or repealed.

This opinion is issued pursuant to Article 26 (3) of the Regulation (EU) 2016/796.

This opinion points out that the national rules adopted or in draft by Estonia are not within the scope of the assessment and/or duplicate requirements in harmonised EU legislation, according to the analysis and the Annex to this opinion.

The applicable EU legislation which is relevant for this opinion is:

- Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety,
- Commission implementing Regulation (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU,
- Commission delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010,
- Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance,
- Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012,
- Commission implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009.

Analysis

As background information it is important to note the timeline of the activities on the review and assessment of the Estonian national rules which started in 2020. This is because the Estonian response to the recent SRD assessment, which is the subject of this technical opinion, requests more help and guidance from the Agency in relation to the result of the assessment. Several attempts have been made over the years to have bilateral meetings with Estonia to go through the results of the various assessments undertaken by the Agency and to explain what is acceptable under the EU legal framework.

Timeline:

- **8 September 2020** the Agency wrote to all Member States setting out the need to review all national rules in the light of the revised 2019 TSI OPE.
- **29 March 2021** Estonia submitted an Excel sheet to the Agency.
- **23 March 2022** the Agency sent their assessment of the rules in the Excel sheet and suggested that a bilateral with Estonia should be arranged to discuss the results of the assessment. There was no response.
- **8 November 2022** a single rule on level crossings was uploaded into SRD by Estonia.
- **5 January 2023** the Agency refused the rule in SRD and wrote to Estonia on 23 January requesting a bilateral meeting with them to discuss the results of the assessment and the other rules that were in the Excel file that needed to be notified.
- **3 March 2023** Estonia responded in SRD that they did not accept the assessment of the Agency. They did not take up the offer of a bilateral meeting.
- **6 March 2023** The Agency provided a detailed response via email requesting that Estonia urgently contacts them to provide more information and to have a discussion. There was no response.
- **30 March 2023** the Agency uploaded a technical opinion OPI 2023/2 into SRD and informed Estonia. The Agency informed Estonia that they remained at Estonia's disposal to discuss this further and to provide them with assistance and help in relation to the clean-up of national rules and the uploading into SRD. There was no response.
- **7 November 2024** Estonia uploaded all the rules into SRD.
- **20 January 2025** the Commission wrote to Estonia seeking confirmation of the contact person on national rules and reiterating the Agency's suggestion of a bilateral.
- **22 January 2025** the Agency wrote to Estonia informing them of the result of the assessment and the next steps and repeating the offer to have a have a bilateral meeting on what can and cannot be accepted as NRs.

The Agency remains open to providing help and having further discussions with Estonia.

In relation to the assessment, the crucial issue was that all the rules were notified under the incorrect scope. The reference to type 1 rules on common safety targets and common safety methods is no longer valid as these have now been harmonised at EU level. This includes both the SMS requirements detailed in EU Regulation 2018/762 and the operational requirements in TSI OPE 2019/773 which also includes Appendix I listing the areas where rules could be created.

It was explained in the technical opinion of OPI 2023/2 that in general, all national rules need to be reviewed against the new EU legal requirements. The EU Member States have a statutory duty under article 8 (2) (b) and 16 (2) (i) of the Safety Directive to review any national rule made redundant by new or revised Union law, including TSIs and to monitor and update the safety regulatory framework including the system of national rules.

At various RISC meetings, particularly following the introduction of new or updated legislation, the Commission have explicitly stated in its presentation on national rules that 'Member States must notify the Commission and the Agency rules that become redundant after publication or revision of the TSIs (Art. 13(1d) IOD)'.

Many of the rules notified in SRD do not consider the development of the EU framework over the last few years. Many of the comments made by Estonia state that this information is needed for the RU and IMs to operate safely, without reference to the need for both RUs and IMs to have detailed risk-based process and procedures in their safety management system which cover those areas that concern Estonia. The effective development of the safety management system and associated processes on issues such as risk assessment,

competence and operational requirements (those covered by the Estonian rules subject to this technical opinion) ensure the efficient and safe cross border operation and promote interoperability.

A detailed review of the rules in SRD, the Agency's assessment and the Estonian's response is set out in the table below.

Rule ID	Rule content and reference in English	Assessment result	Member State's (MS) position on ERA's negative assessment	MS's justification	ERA's final opinion in English
EE SA 1572 1- A	<p>The following legal document is notified by the Member State:</p> <p>Raudteeseadus § 36 "Raudteeohutuse ja -liikluse juhtimise eest vastutavad töötajad" lõiked 1-5</p> <p>The Member State notified Articles 36 sub section 1 to 5 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to roles, responsibilities and competence of staff performing railway safety and traffic management tasks.</p>	<p>This rule is not a permitted under Appendix I of EU Regulation 2019/773 as it relates to specific responsibilities for IM and RU railway staff. This is an area covered by the requirements of the RU and IM safety management system under EU Regulation 2018/762.</p> <p>In addition, the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD.</p> <p>This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.</p>	MS rejected ERA's negative assessment	<p>As Annex I of EU Regulation 2019/773 is approximately 85 pages long, it remains unclear to us which specific point prohibits the requirement set out in §36(1-5). We kindly request a reference to the exact point in Annex I of EU Regulation 2019/773, along with additional explanations on why it is prohibited and how its inclusion hinders interoperability.</p> <p>We agree with you that this point could include a reference to EU Regulation 2019/773 and Regulation 2018/762, which should primarily be followed. However, this point is important as it establishes a fundamental rule that only a competent person can work as a railway employee. It does not impose specific rules.</p> <p>If a reference to EU Regulation 2019/773 and Regulation 2018/762 is added here, that should resolve the issue. If this approach is not acceptable, please let us know how the requirement should be correctly formulated to ensure that railway work is not performed by unqualified individuals?</p>	<p>The adopted rule details elements which are for the RUs and IMs SMS as set out in Commission Delegated Regulation (EU) 2018/762. Each RU and IM must identify roles and responsibilities of staff performing tasks that can affect safety and ensure that they have adequate resource and information and are competent to undertake the tasks.</p> <p>It is not a question of adding a reference to the national rule. The EU Regulation is directly applicable and must be applied by all RUs and IMs. Specifically, this rule overlays requirements that must be managed by the RU and IM.</p> <p>The relevant requirements in Commission Delegated Regulation (EU) 2018/762, in both Annex I and II, are 2.3, 3.1.1, 4.2, 4.6.</p> <p>Therefore, due to the rule covering requirements set out at EU level, the rule is negatively assessed by the Agency.</p>
EE SA 1575 1- A	<p>The following legal document is notified by the Member State:</p> <p>Raudtee tehnikasutuseeskiri § 42 "Kauba- ja reisirongide</p>	<p>This rule is not a permitted under Appendix I of EU Regulation 2019/773 as it relates to passenger and freight train formation. This is an area covered by the requirements of the RU safety management system under EU Regulation 2018/762.</p> <p>If this relates to exceptional transport, only the IM process should be notified</p>	MS rejected ERA's negative assessment	<p>The Member State in their rejection state that:</p> <p>'We kindly request additional explanations on what the correct scope is and how it should be properly assessed and measured. How should the IM process notification be carried out</p>	<p>The scope of the adopted rule covers oversized loads and prohibits them without specifying what specific instructions are needed and the process for requesting them.</p> <p>The Agency can accept rules setting out requirements on exceptional transport. Such rules should set out who is responsible and how the RU can obtain the necessary permissions to operate the</p>

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	<p>koostamine" lõige 3 punkt 7</p> <p>The Member State notified Articles 42 sub section 3, point 7 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to prohibition of oversized loads without specific instructions.</p>	<p>not the technical requirements, as this is for the RUs risk assessment based on the information from the IM.</p> <p>Please review the rule and consider what parts may be accepted under Appendix I and renotify under the correct scope. This is because the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.</p>		<p>correctly? How should the scope of application be defined?</p> <p>In your opinion, is it permissible to include oversized rolling stock in a freight train without following special instructions? This point does not establish national special instructions but simply states that in the case of oversized rolling stock, special instructions must be followed.</p> <p>If necessary, we can add a reference to the relevant EU documents that regulate this matter. If this approach is not acceptable, please let us know the correct way to proceed to ensure safety when handling oversized rolling stock?</p>	<p>exceptional transport. The process itself should be included in the IMs SMS, and this should be part of the cooperation and coordination process between the RU and IM.</p> <p>Therefore, the current rule as notified is negatively assessed by the Agency because it contains requirements which are not in line with the Railway Safety Directive.</p>
EE SA 1576 1- A	<p>The following legal document is notified by the Member State:</p> <p>Raudtee tehnikasutuseeskiri § 42 "Rongiliiklus" lõige 4</p> <p>The Member State notified Articles 42 sub section 4 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to operational information and instructions.</p>	<p>This rule is not permitted under Appendix I of EU Regulation 2019/773 as it is not in line with Appendix C of that Regulation on Safety related communications methodology.</p> <p>Please review the rule and the requirements for written instructions and consider what parts may be accepted under Appendix I as national operational instructions and renotify under the correct scope. This is because the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.</p>	MS rejected ERA's negative assessment	<p>Our initial assessment indicates that this complies with Annex C of EU Regulation 2019/773.</p> <p>It remains unclear to us which specific point prohibits the rule in §36(4). We kindly request a reference to the exact point in Annex C of EU Regulation 2019/773 that prohibits it, along with additional explanations on why it is forbidden and how its existence hinders interoperability.</p> <p>We also request a more detailed explanation regarding the scope—how should it be correctly assessed and determined? How should safety be ensured in this situation if a specific requirement cannot be established for this purpose?</p> <p>Given that common safety methods and guidelines have been harmonized at the EU level but remain very general and do not regulate in sufficient detail the</p>	<p>The adopted rule quotes an Estonian standard EVS 931 <i>Railway applications. Forms of written permits, notices, notices and books used for railway traffic management' or equivalent requirements</i>. It is not acceptable to quote another national standard or reference as a notified rule.</p> <p>Some of the content of the standard may be assessed as a national requirement. However, national requirements must not duplicate or overlay requirements under EU law, in this case requirements under Appendix C of TSI OPE. They should also be notified one by one for each relevant topic.</p> <p>General information on written permits or books is not acceptable as a national rule. This is information that the RU is obliged to put together themselves as an operational process based on information provided by the IM.</p> <p>Therefore, the current rule as notified is negatively assessed by the Agency.</p>

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				<p>requirements for written track and movement authorizations, instructions, orders, and documents, how should we proceed to ensure railway safety in Estonia?</p> <p>For our Class B system, we need specific rules—however, the requirements in Annex C of EU Regulation 2019/773 are too general and do not regulate this at the necessary level. What should we do in this situation to prevent operational issues in railway traffic?</p>	
EE SA 1577 1- A	<p>The following legal document is notified by the Member State:</p> <p style="text-align: center;">Raudtee tehnikasutuseeskirja lise 3</p> <p>The Member State notified Appendix III Articles 36 sub section 4, point 7 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to requirements on signalling.</p>	<p>The majority of this is permitted under Appendix I of EU Regulation 2019/773 as it relates to signalling rules. However, Chapter 8 Article 30 cannot be accepted. This is because the first part relates to the technical requirements for rolling stock and is therefore not a national safety rule under RSD and is also covered by technical requirements for TSI LOC&PAS.</p> <p>The second part gives information on the use of a red light on the front end of the train. This rule cannot be accepted as a safety rule because it potentially introduces additional human and organisational risks to the safety of the operation. The Agency has refused such rules when notified by other Member States. Additional responsibilities are also allocated for staff accompanying a freight train which is also not permitted as this is for the RUs Safety Management System.</p>	MS rejected ERA's negative assessment	<p>As long as ERTMS has not yet been implemented in Estonia, we still need the railway signaling guide. We would like to point out that the entire 1520 mm railway network uses similar signaling systems. We have a Class B signaling system, which has been approved by all relevant parties (railway operators) and is essential for their daily operations to ensure safety. Without these rules, it would not be possible to operate trains between Estonia and third countries. Therefore, it remains unclear which point in the signaling guide does not comply with Annex I of EU Regulation 2019/773. We kindly request more detailed explanations and references to the specific provisions that prohibit or duplicate it. Additionally, we ask for further clarification on the correct scope, how it should be assessed and measured.</p> <p>Please also provide additional explanations on what exactly and how we should notify again?</p>	<p>This adopted rule provides information on requirements of the signalling system in Estonia. As explained in the assessment most of the information can be assessed under Appendix I of the TSI OPE as national signalling rules.</p> <p>However, the parts identified in the assessment are negatively assessed. Estonia was advised to renotify except for the parts that could not be accepted.</p>

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		Please renotify the rule (except Chapter 8 Article 30) under the correct scope. This is because the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.			
EE SA 1578 1- A	<p>The following legal document is notified by the Member State:</p> <p style="text-align: center;">Raudteeseadus § 125 " Raudteeveeremi kasutuseelne kontroll"</p> <p>The Member State notified Article 125 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to requirements on pre use inspection of rolling stock.</p>	This rule is not a permitted under Appendix I of EU Regulation 2019/773 as it relates to the inspection and compatibility of rail vehicles before placing into service. This is because it duplicates and overlays additional requirements to that set out in Appendix D1 on route compatibility checks, D2 on the route book and D3 on ERTMS trackside equipment of EU Regulation 2019/773. This is the responsibility of the RU under their safety management system to look at the compatibility of the train to the relevant infrastructure and that it is safe to operate based on information provided by the IM. In addition, there is also some overlap	MS rejected ERA's negative assessment	<p>In principle, we agree with you that this point should not be overly detailed. Since ERTMS has not yet been implemented in Estonia, it must also be considered that not all of these rules (D1, D2, D3) can currently be applied in Estonia.</p> <p>At the same time, it must be ensured that before new rolling stock is introduced and granted approval for operation on the Estonian market, it undergoes verification—whether the rolling stock is compatible with the railway infrastructure on which it is intended to be used, whether it has been registered in the railway traffic register, and whether it complies with the technical specifications for interoperability. If this verification is not carried out, neither compliance with the TSI nor safety can be ensured. Such verification must be conducted in any case, meaning the obligation to perform this check should be explicitly established. Otherwise, rolling stock that has not undergone proper</p>	<p>This adopted rule provides information on train vehicles and route compatibility checks. This is now a requirement under Appendix D1 of the TSI OPE on route compatibility checks.</p> <p>Furthermore, under EU legislation the IM does not retain the responsibility for checking vehicles. Their role is to provide all the information necessary for the RU to ensure, via their SMS processes, that the vehicle is safe for the route.</p> <p>If at the request of the RU, the IM conducts inspections then this is a contractual issue between the two parties and not part of a national rule.</p> <p>Regulation 2018/762 Annex I point 3.1.1, 5.1.3, 5.2 and 5.4 sets out requirements for the RU to have in place in their SMS that should cover the issue of new or upgraded rolling stock that is introduced onto the rail network of Estonia.</p> <p>Compliance with the requirements of the relevant TSIs are done via the authorisation to place on the market by NoBos and DeBos, the route compatibility checks undertaken by the RU before the rolling stock is introduced and the asset management requirements supported by the risk assessment processes in the RUs SMS once the vehicle is operational.</p>

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				<p>verification may start operating on the railway.</p> <p>Railway infrastructure managers should retain the right to conduct such inspections to ensure that the requirements set out in EU Regulation 2019/773 are met and that the rolling stock is compatible with the specific characteristics of the local railway infrastructure. If this approach is not acceptable, please let us know the correct way to proceed to ensure safety is maintained?</p>	<p>Therefore, the current rule as notified is negatively assessed by the Agency due because it contains requirements which are not in line with EU railway legislation.</p>
EE SA 1579 1- A	<p>The following legal document is notified by the Member State:</p> <p style="text-align: center;">Raudtee tehnikasutuseeskiri § 15</p> <p>The Member State notified Article 15 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to the IM developing guidelines on ensuring safe traffic on their infrastructure.</p>	<p>This rule is not a permitted under Appendix I of EU Regulation 2019/773 as it relates to the management of the infrastructure which is for the IMs safety management system on asset management.</p> <p>In addition, the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMS and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.</p>	MS rejected ERA's negative assessment	<p>In principle, we agree with you that this point should not be overly detailed. We will revise it and include references to EU Regulation 2019/773, which already regulates this area. However, railway infrastructure managers must retain the right to establish guidelines ensuring safe traffic on their infrastructure, based on EU Regulation 2019/773. Otherwise, they would not be able to ensure railway safety while taking into account the specific characteristics of the infrastructure. If this approach is not acceptable, please let us know the correct way to proceed?</p>	<p>This adopted rule permits IMs to develop guidelines for the organisation of train traffic and shunting operations by means of signalling and communication equipment. It is not clear if these guidelines are just for the IM or for the RU as well.</p> <p>If they are for the IM, Regulation 2018/762 requirement 5 sets out elements that the IM needs to have in their SMS to ensure the safe management of traffic operation. This information should be shared with the RU, but it should not be an obligatory rule.</p> <p>If these are for the RU, then these become hidden IM rules that set requirements on the RU which is not the responsibility of the IM. It is for the RU to take forward what is needed to operate safely on the relevant IM infrastructure and incorporate it in their SMS by means of specific operational processes. This should be based on the outcome of their risk assessments and information (not rules) provided by the IM.</p> <p>Considering the justification above, having in mind the perspective provided in the European</p>

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					<p>legislation, such rules should be removed due to the lack of transparency in their application as well as in responsibility held by different actors of the railway sector.</p> <p>Therefore, the current rule as notified is negatively assessed by the Agency because it contains requirements which are not in line with EU railway legislation.</p>
EE SA 1580 1- A	<p>The following legal document is notified by the Member State:</p> <p style="text-align: center;">Raudtee tehnikasutuseeskirja § 40 "Rongide liikumine kord"</p> <p>The Member State notified Article 40 of the adopted document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to normal and degraded operation.</p>	<p>This rule is not a permitted under Appendix I of EU Regulation 2019/773 as it relates to information on train movement procedure and should be for the RUs safety management system based on the information provided by the IM.</p> <p>Some of the information also overlap and duplicate the common operational rules in Appendix B of EU Regulation 2019/773. Article 40 (2) may be accepted as speeds in degraded mode.</p> <p>Please review the rule against the requirements of Appendix B C and the issue of speeds in degraded mode and consider what parts may be accepted under Appendix I and renotify under the correct scope. This is because the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.</p>	MS rejected ERA's negative assessment	We agree with you that this point should not be overly detailed. We will revise it and include references to EU Regulation 2019/773, which already governs this area. However, railway infrastructure managers must retain the right to establish guidelines ensuring safe traffic on their infrastructure, based on EU Regulation 2019/773. Otherwise, they would not be able to guarantee railway safety due to the specific characteristics of the infrastructure. If this approach is not acceptable, please let us know the correct way to proceed?	<p>This adopted rule sets out specific requirements on the RUs in relation to operation on the network during normal and degraded operation. This is the responsibility of the RU and not be set out in a national rule or become a responsibility of the IM.</p> <p>Some of the elements duplicate what is set out in Appendix B on the common operational rules (COR). The TSI OPE is a directly applicable legislation and for the RU and the IM to consider in their SMS. If a COR needs to be updated or a new COR introduced, Estonia should put in a change request for the TSIs to the Agency.</p> <p>Some parts in relation to speeds in degraded mode can be assessed as falling under the appropriate area listed in Appendix I of TSI OPE. Therefore, the current rule as notified is negatively assessed by the Agency.</p> <p>Please note the Agency made an error in the original assessment and quoted Appendix C instead of Appendix B.</p>

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EE SA 1582 1- D	<p>The following legal document is notified by the Member State:</p> <p style="text-align: center;">Raudteetöötaja tervisenõuded ja tervisekontrolli kord § 2 "Nõuded raudteetöötaja nägemisele ja kuulmisele"</p> <p>The Member State notified Article 2 of the draft document as a national rule type 1 'Rules concerning existing national safety targets and safety methods'.</p> <p>The rule relates to hearing and sight requirements.</p>	<p>This rule is not a permitted under Appendix I of EU Regulation 2019/773 as it relates to hearing requirements. Appendix I only permits national rules on alcohol, drugs and psychotropic medication.</p> <p>In addition, the scope is also incorrect. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules.</p>	MS rejected ERA's negative assessment	<p>As Annex I of EU Regulation 2019/773 spans approximately 85 pages, we are unclear on which specific point prohibits the requirement in Section 2. Could you please provide us with a reference to the specific point in Annex I of EU Regulation 2019/773, along with explanations as to why it is prohibited and how its existence hinders interoperability? We believe you agree with us on the crucial importance of ensuring railway staff can see and hear well for safety on the railways. In this context, how should safety be ensured if this specific requirement cannot be enforced?</p>	<p>This draft rule sets out hearing and sight requirements for railway workers.</p> <p>Specific medical requirements in national rules hinder interoperability because in case an RU crosses the border, they must consider different national rules.</p> <p>It is often a burden for cross border issues where Member States have different requirements on medical fitness or different levels of those requirements (from high level to very complex and detailed requirements). If a rule is different across the various areas of operation between MS, this can lead to issues with application and different requirements for the same operation and the same staff depending on where the RU operates.</p> <p>This is why the SMS has been developed for the RU to have the same processes when they operate across several Member States. These processes which must include fitness for work of all staff will be adapted, depending on the different operational context that the RU should consider, when they operate in several Member States.</p> <p>The issue of medical fitness of staff has been discussed in several RISC meetings. The Commission has stated that medical fitness requirements for train drivers is covered by the Train driver Directive 2007/59/EC. Medical requirements for (1) staff accompanying a train, (2) staff preparing trains (3) IM signalling staff and train despatchers are covered by 4.7 of the TSI OPE.</p> <p>All other medical requirements for staff having a role that can affect safety of the operation are for</p>

Rule ID	Rule content and reference in English	Assessment result	Member State's (MS) position on ERA's negative assessment	MS's justification	ERA's final opinion in English
					<p>the RUs or IMs SMS. There is therefore no room for further national rules in this area.</p> <p>NSAs also have tools within their supervision activities, for instance as provided by EU Regulation 2018/761, to check and re-enforce the importance of the effective application of the SMS including fitness for work and medical requirements.</p> <p>Therefore, the current rule as notified is negatively assessed by the Agency because it contains requirements which are not in line with EU railway legislation.</p>

The opinion

The Agency is of the opinion that the provisions in the seven (7) adopted rules and the one (1) draft rule of Estonia are either not compliant with relevant EU legal requirements or do not meet the scope of notification of a national rule in the field of safety, according to Article 8 of Directive (EU) 2016/798 on railway safety, as described in part 3 Analysis of this opinion.

For this reason, in accordance with Article 25 and Article 26 (3) of Regulation (EU) 2016/796, the Agency with this opinion confirms its negative assessment.

This opinion is addressed to Estonia, with a copy to the European Commission (DG Move).

Valenciennes, /04/2025

Pio GUIDO
Acting Executive Director

Annex 1

Impact Note

Regarding seven (7) adopted and one (1) draft national rule by Estonia setting requirements on several operational aspects.

Issued as per Art. 8(1) of Regulation (EU) 2016/796 and the Impact Assessment procedure adopted by the ERA Management Board (Decision n.290, 16/03/2022)

1. Context and assessment of impacts

1.1. The national rule in object

In line with article 26 (3) of Regulation (EU) 2016/796, this opinion covers the examination of seven (7) adopted rules and one (1) draft national rule notified by Estonia in the Single Rules Database (SRD) on 7 November 2024.

The Agency assessed them and reached the conclusion (also recorded in the SRD) that the notified rules contain requirements which according to the Agency's opinion:

*were not notified using the correct scope according to Article 8 of Directive (EU) 2016/798 on railway safety; and
are not in line with the EU legal framework, mainly Regulation (EU) 2019/773 (TSI OPE) and Regulation (EU) 2018/762 establishing common safety methods on safety management system requirements (CSM-SMS)*

1.2. Analysis performed

The Agency shared its negative assessment with Estonia on the 6 January 2025 via SRD and also via email on 22 January 2025. Estonia notified the Agency via SRD its rejection of the Agency's negative assessment of the seven (7) adopted national rules and one (1) draft rule on 5 March 2025.

The negatively assessed rules are provisions contained in several adopted legal documents and one draft legal document. Details about the specific legal acts concerned are available in the SRD and also in annex 2 of this technical opinion.

In chapter 3 of this opinion the Agency provides an overview of the rules. In particular, all the various rules were:

notified under the incorrect scope. The reference to type 1 rules on common safety targets and common safety methods is no longer valid as these have now been harmonised at EU level. This includes both the SMS requirements detailed in EU Regulation 2018/762 and the operational requirements in TSI OPE 2019/773 which also includes Appendix I listing the areas where rules could be created. The Commission has informed Member States that no further rules will be permitted under type 1 or type 2 national safety rules of the RSD. This is because CSMs and CSTs have been harmonised at EU level and therefore there is no longer any room for national rules in this domain.

in areas already regulated in EU legal framework, including Regulation (EU) 2019/773 and Regulation (EU) 2018/762. The TSI OPE Regulation (EU) 2019/773 is directly applicable. This means that its provisions shall not be duplicated or further supplemented in the national law. It is for the RU/IM to develop their respective SMSs on the basis of the requirements specified in EU law, including the TSI OPE and the CSM-SMS Regulation, (EU) 2018/762. A national rule shall not introduce additional requirements for the SMS other than those set out in EU legislation. Moreover, identification and allocation of roles and responsibilities to staff, including staff performing safety-critical tasks, is a responsibility of the RU (or IM for their staff) and should be a part of the SMS of the RU/IM, according to requirement 2.3.1 of Annex I/II of CSM SMS Regulation.

1.3. Assessment of impacts

The seven (7) adopted national rules and the one (1) draft national rule of Estonia were not notified under the correct scope in accordance with the EU Railway Safety Directive and concern areas already regulated within the EU legal framework.

They fall within the scope of the Light Impact Assessment 'Revision of the Common Safety Methods on Conformity Assessment and the Common Safety Methods on Supervision' performed by the Agency in February 2017 and of the Full Impact Assessment on the TSI OPE Revision carried out in 2018. The impacts were therefore already adequately assessed and it is confirmed that these rules would compromise uniformity of application of well-established EU requirements on SMS and increase the risk of low transparency of the national rules framework that stakeholders have to comply within Estonia.

In particular the rules negatively assessed do not fall under a valid area for national rules, or they duplicate or are not in line with requirements and/or procedures to be addressed in the companies' Safety Management System. It is for the SMS of RU/IM to develop their processes and procedures on the basis of the requirements specified in EU law, including TSI OPE Regulation (EU) 2019/773. A national rule should not prescribe additional requirements for the safety management systems of railway undertakings and infrastructure managers since such requirements have been defined in Regulation (EU) 2018/762.

Interoperability and coherence of the EU legal framework across the Union risk to be weakened by duplicating or further supplementing, in the national law, requirements already covered (in a harmonised way) at European level, going against the policy goal of reducing national rules and creating unnecessary burden on stakeholders (including unnecessary efforts to ensure the enforcement of the additional national rules on top of all other existing oversight requirements pertaining to EU law), with no (or doubtful) benefit.

1.4. Stakeholders affected

Railway undertakings (RU)	<input checked="" type="checkbox"/>	Member States (MS)	<input checked="" type="checkbox"/>
Infrastructure managers (IM)	<input checked="" type="checkbox"/>	Third Countries	<input type="checkbox"/>
Manufacturers	<input type="checkbox"/>	National safety authorities (NSA)	<input checked="" type="checkbox"/>
Keepers	<input type="checkbox"/>	European Commission (EC)	<input checked="" type="checkbox"/>
Entity Managing the Change (EMC)	<input type="checkbox"/>	European Union Agency for Railways (ERA)	<input checked="" type="checkbox"/>
Notified Bodies (NoBo)	<input type="checkbox"/>	Shippers	<input type="checkbox"/>
Associations	<input type="checkbox"/>	Other (Please specify) ...	<input type="checkbox"/>

2. Preferred option

2.1. Recommendation

No alternative options are to be assessed and it is confirmed a negative assessment of the seven adopted rules and one draft rule in question notified by Estonia.